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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,498	10/15/2001	Adrian Clausell	2055-181	4848

22471 7590 05/20/2004

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EXAMINER
PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	**Application No.**	**Applicant(s)**	
	09/978,498	CLAUSELL ET AL.	
	Examiner	**Art Unit**	
	Francisco C Prats	1651	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *10 May 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☒ they raise the issue of new matter (see Note below);

(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *see attachment*.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attachment*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *5-14,16-20 and 23-55*.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Francisco C Prats
Primary Examiner
Art Unit: 1651

ATTACHMENT TO ADVISORY ACTION

The after-final amendment filed May 7, 2004, has been received. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

The after-final amendment filed May 7, 2004, will not be entered because it raises new issues for search and consideration. Specifically, the claims now require the analyte composition to be added so as to "layer" the composition on to the cells. This layering step has not been searched or considered previously. Also, the new recitation "minimal mixing" raises a new issue under § 112, second paragraph, since it is not clear on the record how much mixing is encompassed by the recitation "minimal" and how much mixing is not encompassed. Because the recitation "minimal" fails to clearly delineate between claim-encompassed subject matter and non-claim-encompassed subject matter, a new rejection for indefiniteness would be required. Thus, the amendment clearly raises a new issue for search and consideration and non-entry is clearly proper at this stage of prosecution.

All of applicant's argument has been fully considered but is not persuasive of error. At the outset it is noted that applicant's argument almost entirely assumes entry of the

non-entered after-final amendment. In view of non-entry of the amendment most of applicant's argument is technically directed to limitations not present in the claims. However, applicant's argument has been addressed to the extent possible.

In view of the non-entry of the amendment, the rejections under § 112, second paragraph, cannot be withdrawn. Moreover, as discussed above, entry of the amendment raises new issues under that statutory provision.

With respect to the anticipation rejection over Wansink, it cannot be agreed that the proposed new language overcomes that reference. Technically, the precipitates used for analysis in Wansink were in fact prepared from intact metabolically active cells. Thus, the intact cells were assayed. In order for the claims to read as applicant desires, applicant would have to insert at claim 5, line 14, after the word "cell", a recitation stating something like --

, in a manner that does not damage the cell,

--.

Thus, while applicant's argument is understood, it is respectfully submitted that Wansink assays intact whole cells as required by the claims, albeit in a manner which ultimately destroys the cells. Absent some language in the claims

clarifying this point, Wansink would remain applicable to the claims despite the proposed amendment.

With respect to the § 102 rejection over Zhang, note that the after-final rejection of does not contain such a rejection. The rejection of claims over Zhang is under § 103(a) only.

With respect to the failure of Lucas, Landrum, Wansink and Zhang to disclose or suggest a non-homogeneous or layered assay, note specifically that this limitation was not present in the claims when the final rejection was made. That is, these references were not applied to claims containing such a limitation. Because of the non-entry of the after-final amendment at issue, applicant is technically arguing about a limitation not present in the claims. Moreover, in view of the fact that the new limitation has not been searched or considered previously, applicant's argument regarding allowability over the art is premature.

As to the increased amounts of DMSO recited in claims compared to the cited prior art, it is again pointed out that Lucas explicitly states that effective amounts of solubilizers can be determined through routine experimentation. Thus, the artisan of ordinary skill clearly would have been able to determine suitable concentrations of solubilizing agents, including those recited in the claims.

Further still, it is again noted, as argued by applicant, that Wansink assays the cells using a method which ultimately destroys the cells. However, even if the claims were amended in a fashion such that Wansink could not be applied under § 102, the import of the Wansink disclosure is that the claimed permeabilizing agent, glycerol, was known to be used for the purpose of permeabilizing cells so as to allow for entry into cells of compounds used for analysis of said cells in intact form. Contrary to applicant's argument, one of ordinary skill would not take from Wansink the teaching that the use of glycerol as a permeabilizing agent requires cell destruction. Rather, the artisan of ordinary skill would have recognized that the permeabilization of the cells is clearly unrelated to the later-performed assay methods.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP